

**Appl. No.** : 09/916,858  
**Filed** : July 27, 2001

### **REMARKS**

Claims 1-23 and 25-43 are pending in this application. Claim 24 has been canceled as drawn to nonelected subject matter. Claims 10, 32, 37, 39, 42, and 43 have been amended. Support for the amendments is found in the specification and claims as filed.

#### **Response to Restriction Requirement**

A Restriction Requirement has been imposed in this application. In connection therewith, it is asserted that the application claims the following inventions: Claims 1-23 and 25-43, drawn to a method and device for measuring an analyte in biological fluid, classified in class 600, subclass 345 (Group I); and Claim 24, drawn to a combined angiogenic/bioprotective membrane, classified in class 204, subclass 403.01 (Group II). Applicants hereby affirm the election, without prejudice, of the invention of Group I, including Claims 1-23 and 25-43, drawn to a method and device for measuring an analyte in biological fluid, and cancel without prejudice Claim 24 as drawn to a non-elected invention.

#### **Filing Date of Pending Claims**

Applicants respectfully acknowledge the conclusion that Claims 1-3, 8-12, 15-17, 20, 22, 23, and 25-31 find support in the parent applications 09/447,227 and 08/811,473, and therefore are entitled to the filing date of March 4, 1997.

Applicants note that it has been concluded that Claims 4-7, 13, 14, 18, 19, 21, and 32-43 do not find support in the parent applications and therefore are entitled to the filing date of this application, July 27, 2001. Applicants respectfully disagree with this conclusion as to Claim 7. The parent applications define "sensor interface" to refer to "that region wherein a biological sample (e.g., blood or interstitial fluid) or a portion thereof contacts (directly or after passage through one or more membranes or layers) an enzyme (e.g., glucose oxidase)." See col. 4, line 41-57 of U.S. 6,001,067, corresponding to parent application 08/811,473. Thus, the "biostable layer" or "bioprotective layer" of the parent application (see col. 12, ln. 53 of U.S. 6,001,067) is inclusive of that region where the biological sample contacts an enzyme.

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**Obviousness-Type Double Patenting Rejection**

Claims 1, 17, 20, 22, 23, 27, 28, and 30 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-9 of U.S. Patent No. 6,001,067. Applicants herewith submit a terminal disclaimer to overcome this rejection.

**Provisional Obviousness-Type Double Patenting Rejection**

Claim 1 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of copending U.S. Application No. 09/447,227. Applicants herewith offer to submit a terminal disclaimer if necessary to overcome this rejection once the patented claims become available.

**Provisional Obviousness-Type Double Patenting Rejection**

Claim 1 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of copending U.S. Application No. 09/489,588. Applicants herewith offer to submit a terminal disclaimer if necessary to overcome this rejection once the patented claims become available.

**Claim Rejections - 35 U.S.C. § 112, first paragraph**

Claims 7, 8, and 32-43 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement.

It is asserted that Claims 7 and 8, which recite that the biostable layer has a tissue interface, are contradictory in that the only disclosed biostable layer is the bioprotective layer, but the angiogenic layer is the outermost layer of the membrane in contact with tissue. Although it is true that the angiogenic layer is the outermost layer, it is also true that the angiogenic layer comprises a through-porosity to the bioprotective membrane. Paragraph 77 of the present application states, "[t]he angiogenic layer comprises pores sizes of about 0.5  $\mu\text{m}$  to about 20  $\mu\text{m}$ , and more preferably about 1.0  $\mu\text{m}$  to about 10  $\mu\text{m}$ , sizes that allow most substances to pass through, including, *e.g.*, macrophages." Thus the biological fluid is allowed to pass through the angiogenic layer to the bioprotective layer, which functions to protect the underlying sensor from

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the effects of this biological tissue. Together, the angiogenic layer and bioprotective membrane function as the tissue interface.

It is asserted that Claim 32 (from which claims 33-43 depend), which recites that the bioprotective membrane has a tissue interface, is contradictory in that the angiogenic layer is the outermost layer of the membrane in contact with tissue. Claim 32 as amended no longer refers to a bioprotective membrane.

In view of the foregoing remarks and amendments, Applicants respectfully request withdrawal of the rejections.

**Claim Rejections - 35 U.S.C. § 112, second paragraph**

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, as indefinite in that there is no antecedent basis for the sensor interface. Claim 10 has been amended to depend from Claim 9. In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection.

**Claim Rejection - 35 U.S.C. § 102(e)**

Claims 32, 35, 36, and 37 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. 6,454,710 to Ballerstadt et al. Ballerstadt et al. disclose an implantable device for detection of an analyte through a body tissue (see col. 10, lines 39-56). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." See, e.g., *In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Ballerstadt et al. does not disclose every element of Applicants' claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(e).

The device described by Ballerstadt includes a membrane system, however no electronics are provided as part of the implanted device, because the electronics of the Ballerstadt et al. device are housed in a separate device located outside of the body in the vicinity of the implant. Because Ballerstadt et al. do not disclose "[a]n implantable device for continuous glucose monitoring comprising ... a housing comprising an electronic circuit." Accordingly, Applicants respectfully request that the rejection be withdrawn.

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**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 1-6, 8-12, 17, 19, 22, 23, 25-24, and 37-43 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. 5,964,993 to Blubaugh, Jr. et al. in view of U.S. 5,706,807 to Picha. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Likewise, if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Blubaugh, Jr. et al. discloses the incorporation of anti-inflammatories into an implantable device that diffuse out of the device and keep the surrounding area free from leukocytes associated with a foreign body response (see col. 10, ln. 35-49). In contrast, Picha teaches “the use of foam on the surface of the described implants ... not only allows the invasion of cells and vascularity, but also promotes continued inflammation and fibrosis.” (col. 5, ln. 53-59).

Accordingly, there is no suggestion or motivation to combine a pro-inflammatory material onto a device with anti-inflammatory substances incorporated therein, because the teachings of the cited references are contradictory, and to modify the teachings of Blubaugh, Jr. et al. as suggested would change the principle of operation of the Blubaugh device. A *prima facie* case of obviousness therefore cannot be established, and Applicants respectfully request that the rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Blubaugh, Jr. et al. in view of Picha as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-24, and 37-43, further in view of U.S. 6,011,984 to Van Antwerp et al.

As discussed above, there is no suggestion or motivation to combine the teachings of Blubaugh, Jr. et al. and Picha. Van Antwerp et al. does not include disclosure sufficient to

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overcome the deficiencies of Blubaugh, Jr. et al. and Picha. Accordingly, Applicants respectfully request that the rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Blubaugh, Jr. et al. in view of Picha as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-24, and 37-43, further in view of U.S. 5,322,063 to Allen et al.

As discussed above, there is no suggestion or motivation to combine the teachings of Blubaugh, Jr. et al. and Picha. Allen et al. does not include disclosure sufficient to overcome the deficiencies of Blubaugh, Jr. et al. and Picha. Accordingly, Applicants respectfully request that the rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 35 and 36 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Blubaugh, Jr. et al. in view of Picha as applied to claims 1-6, 8-12, 17, 19, 22, 23, 25-24, and 37-43, further in view of U.S. 4,436,094 to Cerami.

As discussed above, there is no suggestion or motivation to combine the teachings of Blubaugh, Jr. et al. and Picha. Cerami does not include disclosure sufficient to overcome the deficiencies of Blubaugh, Jr. et al. and Picha. Accordingly, Applicants respectfully request that the rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 38-43 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ballerstadt et al. To articulate a *prima facie* case of obviousness, the PTO must, *inter alia*, cite prior art that teaches or suggests all the claimed limitations. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). As discussed above in regard to the rejection under 35 U.S.C. § 102(e), Ballerstadt et al. fails to teach or suggest all of the claimed limitations, namely, “[a]n implantable device for continuous glucose monitoring comprising ... a housing comprising an electronic circuit.” Accordingly, a *prima facie* case of obviousness against Claims 38-43 cannot be made, and Applicants respectfully request withdrawal of the rejection.

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**Allowable Subject Matter**

Claims 13, 14, 20, and 21 have been objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants acknowledge the indication of allowability of these claims if redrafted into independent form, but respectfully assert that the base claim and any intervening claims are in condition for allowance.

**Conclusion**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

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